

CLAIMS:

1. A pharmaceutically acceptable oral formulation comprising core material which comprises a therapeutically effective amount of a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, solvate or derivative thereof, which core material is provided with a substantially water resistant coating comprising one or more substantially water resistant materials.
2. A pharmaceutically acceptable oral formulation according to claim 1, wherein said 5-HT-receptor agonist is selected from the group consisting of sumatriptan, zolmitriptan, naratriptan and rizatriptan, and pharmaceutically acceptable salts, solvates and derivatives thereof.
3. A pharmaceutically acceptable oral formulation according to claim 2, wherein said 5-HT-receptor agonist is sumatriptan, or a pharmaceutically acceptable salt or solvate thereof.
4. A pharmaceutically acceptable oral formulation according to claim 4, wherein said 5-HT-receptor agonist is sumatriptan succinate.
5. A pharmaceutically acceptable oral formulation according to any of claims 1 to 4, which is substantially free of degradation products associated with exposure of a 5-HT-receptor agonist to ambient moisture.
6. A pharmaceutically acceptable oral formulation according to claims 4 and 5, which is a tablet formulation including 25mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

7. A pharmaceutically acceptable oral formulation according to claim 6, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.
8. A pharmaceutically acceptable oral formulation according to claim 7, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.
9. A pharmaceutically acceptable oral formulation according to claims 4 and 5, which is a tablet formulation including 25mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.
10. A pharmaceutically acceptable oral formulation according to claim 9, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.
11. A pharmaceutically acceptable oral formulation according to claim 10, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

12. A pharmaceutically acceptable oral formulation according to claims 4 and 5, which is a tablet formulation including 100mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

13. A pharmaceutically acceptable oral formulation according to claim 12, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

14. A pharmaceutically acceptable oral formulation according to claim 13, wherein there is present under storage conditions of about 1 month at 25EC and 60% relative humidity, about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

15. A pharmaceutically acceptable oral formulation according to claims 4 and 5, which is a tablet formulation including 100mg of sumatriptan succinate, and wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

16. A pharmaceutically acceptable oral formulation according to claim 15, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

17. A pharmaceutically acceptable oral formulation according to claim 16, wherein there is present under storage conditions of about 1 month at 40EC and 75% relative humidity, about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide.

18. A pharmaceutically acceptable oral formulation according to any of claims 1 to 17, wherein said one or more substantially water resistant materials comprise one or more waxes, or one or more wax derivatives.

19. A tablet formulation comprising core material which comprises a therapeutically effective amount of sumatriptan succinate, together with a substantially water resistant coating provided to said core material and comprising one or more waxes, or one or more wax derivatives, characterised in that said tablet formulation contains about 25mg of sumatriptan succinate and under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation.

20. A tablet formulation according to claim 19, wherein less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 25EC and 60% relative humidity.

21. A tablet formulation according to claim 20, wherein about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 25EC and 60% relative humidity.

22. A tablet formulation comprising core material which comprises a therapeutically effective amount of sumatriptan succinate, together with a substantially water resistant

coating provided to said core material and comprising one or more waxes, or one or more wax derivatives, characterised in that said tablet formulation contains about 25mg of sumatriptan succinate and under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation.

23. A tablet formulation according to claim 22, wherein less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 40EC and 75% relative humidity.

24. A tablet formulation according to claim 23, wherein about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 40EC and 75% relative humidity.

25. A tablet formulation comprising core material which comprises a therapeutically effective amount of sumatriptan succinate, together with a substantially water resistant coating provided to said core material and comprising one or more waxes, or one or more wax derivatives, characterised in that said tablet formulation contains about 100mg of sumatriptan succinate and under storage conditions of about 1 month at 25EC and 60% relative humidity, less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation.

26. A tablet formulation according to claim 25, wherein less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 25EC and 60% relative humidity.

27. A tablet formulation according to claim 26, wherein about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 25EC and 60% relative humidity.

28. A tablet formulation comprising core material which comprises a therapeutically effective amount of sumatriptan succinate, together with a substantially water resistant coating provided to said core material and comprising one or more waxes, or one or more wax derivatives, characterised in that said tablet formulation contains about 100mg of sumatriptan succinate and under storage conditions of about 1 month at 40EC and 75% relative humidity, less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation.

29. A tablet formulation according to claim 28, wherein less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 40EC and 75% relative humidity.

30. A tablet formulation according to claim 29, wherein about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide is present in the tablet formulation, under storage conditions of about 1 month at 40EC and 75% relative humidity.

31. A formulation according to any of claims 18 to 30, wherein said wax is selected from the group consisting of beeswax, shellac, carnauba wax, spermaceti, lanolin, jojoba oil, candellila wax, ozocerite and opaglos 6000 P.

32. A formulation according to claim 31, wherein said wax is selected from the group consisting of carnauba wax, beeswax and opaglos 6000 P.

33. A formulation according to any of claims 1 to 32, wherein said substantially water-resistant coating further comprises one or more coating excipient materials, solvents for the waxes and plasticizers to coat solid formulations.
34. A formulation according to any of claims 1 to 33, wherein said substantially water-resistant coating is directly applied to the core material.
35. A formulation according to any of claims 1 to 34, wherein core material comprises sumatriptan succinate, mannitol or dibasic calcium phosphate or calcium carbonate, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.
36. A formulation according to claim 35, wherein core material comprises sumatriptan succinate, mannitol, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.
37. A formulation according to claim 35, wherein core material comprises sumatriptan succinate, dibasic calcium phosphate, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.
38. A formulation according to claim 35, wherein core material comprises sumatriptan succinate, calcium carbonate, hypromellose and / or microcrystalline cellulose, croscarmellose sodium and magnesium stearate.
39. A formulation according to claim 35, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w mannitol or dibasic calcium phosphate or calcium carbonate, about 1 to 10% w/w hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

40. A formulation according to claim 39, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w mannitol, about 1 to 10% w/w hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

41. A formulation according to claim 39, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w dibasic calcium phosphate, about 1 to 10% w/w hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

42. A formulation according to claim 39, which comprises about 20 to 55 % w/w sumatriptan succinate, about 20 to 50 % w/w calcium carbonate, about 1 to 10% w/w hypromellose and / or microcrystalline cellulose, about 1 to 5 % w/w croscarmellose sodium and about 0.5 to 2 % w/w magnesium stearate.

43. Use of one or more waxes, or one or more wax derivatives, to inhibit degradation of a 5-HT-receptor agonist susceptible to degradation on exposure to ambient moisture, wherein said one or more waxes, or one or more wax derivatives, provides a substantially water resistant coating to a core material comprising a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, solvate or derivative thereof, of a pharmaceutically acceptable oral formulation.

44. Use according to claim 43, wherein said 5-HT-receptor agonist is selected from the group consisting of sumatriptan, zolmitriptan, naratriptan and rizatriptan, and pharmaceutically acceptable salts, solvates and derivatives thereof.

45. Use according to claim 44, wherein said 5-HT-receptor agonist is sumatriptan, or a pharmaceutically acceptable salt or solvate thereof.

46. Use according to claim 45, wherein said 5-HT-receptor agonist is sumatriptan succinate.



47. Use according to claim 46, where said formulation comprises a tablet formulation including 25mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

48. Use according to claim 47, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

49. Use according to claim 47, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

50. Use according to claim 46, where said formulation comprises a tablet formulation including 25mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

51. Use according to claim 50, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

52. Use according to claim 51, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

53. Use according to claim 46, where said formulation comprises a tablet formulation including 100mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

54. Use according to claim 53, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

55. Use according to claim 54, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

56. Use according to claim 46, where said formulation comprises a tablet formulation including 100mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide under storage conditions of about 1 month at 40EC and 75% relative humidity.

57. Use according to claim 56, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

58. Use according to claim 57, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide under storage conditions of about 1 month at 40EC and 75% relative humidity.

59. Use according to any of claims 43 to 58, wherein said wax is selected from the group consisting of beeswax, shellac, carnauba wax, spermaceti, lanolin, jojoba oil, candellila wax, ozocerite and opaglos 6000 P.

60. Use according to claim 59, wherein said wax is selected from the group consisting of carnauba wax, beeswax and opaglos 6000 P.

61. A method of substantially inhibiting the formation, in a pharmaceutically acceptable oral formulation, of degradation products associated with exposure of a 5-HT-receptor agonist to ambient moisture, which method comprises providing core material comprising a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, solvate or derivative thereof, with a substantially water resistant coating comprising one or more substantially water resistant materials.

62. A method according to claim 61, wherein said 5-HT-receptor agonist is selected from the group consisting of sumatriptan, zolmitriptan, naratriptan and rizatriptan, and pharmaceutically acceptable salts, solvates and derivatives thereof.

63. A method according to claim 62, wherein said 5-HT-receptor agonist is sumatriptan, or a pharmaceutically acceptable salt or solvate thereof.

64. A method according to claim 63, wherein said 5-HT-receptor agonist is sumatriptan succinate.

65. A method according to claim 64, where said formulation comprises a tablet formulation including 25mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

66. A method according to claim 65, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

67. A method according to claim 66, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

68. A method according to claim 64, where said formulation comprises a tablet formulation including 25mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.65% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

69. A method according to claim 68, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of

[3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

70. A method according to claim 69, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

71. A method according to claim 64, where said formulation comprises a tablet formulation including 100mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

72. A method according to claim 71, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

73. A method according to claim 72, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.50% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 25EC and 60% relative humidity.

74. A method according to claim 64, where said formulation comprises a tablet formulation including 100mg of sumatriptan succinate, and inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.65% by

weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide under storage conditions of about 1 month at 40EC and 75% relative humidity.

75. A method according to claim 74, wherein inhibition of said degradation products is such that there is present in said tablet formulation less than about 0.60% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide, under storage conditions of about 1 month at 40EC and 75% relative humidity.

76. A method according to claim 75, wherein inhibition of said degradation products is such that there is present in said tablet formulation about 0.55% by weight of [3-[2-(dimethylamino)ethyl]-2-[[3-[2-(dimethylamino)ethyl]-1H-indol-5-yl]methyl]-1H-indol-5-yl]-N-methylmethanesulphonamide under storage conditions of about 1 month at 40EC and 75% relative humidity.

77. A method according to any of claims 61 to 76, wherein said one or more substantially water resistant materials comprise one or more waxes, or one or more wax derivatives.

78. A method according to claim 77, wherein said wax is selected from the group consisting of beeswax, shellac, carnauba wax, spermaceti, lanolin, jojoba oil, candellila wax, ozocerite and opaglos 6000 P.

79. A method according to claim 78, wherein said wax is selected from the group consisting of carnauba wax, beeswax and opaglos 6000 P.

80. A method of treating a condition prevented, ameliorated or eliminated by administration of a 5-HT-receptor agonist, which method comprises administering to a human patient suffering from or susceptible to such a condition a therapeutically effective amount of a formulation according to any of claims 1 to 42.

81. A method according to claim 80, wherein said condition being treated is selected from the group consisting of migraine, cluster headache, chronic paroxysmal hemicrania, headache associated with vascular disorders, tension headache and paediatric migraine.

82. A method according to claim 81, wherein said condition is migraine.

83. Use of a therapeutically effective amount of a 5-HT-receptor agonist present in a core material, or a pharmaceutically acceptable salt, solvate or derivative thereof, and a substantially water resistant coating for said core material comprising one or more substantially water resistant materials, in the manufacture of a formulation according to any of claims 1 to 42, for the treatment of a condition prevented, ameliorated or eliminated by administration of a 5-HT-receptor agonist.

84. Use according to claim 83, wherein said condition being treated is selected from the group consisting of migraine, cluster headache, chronic paroxysmal hemicrania, headache associated with vascular disorders, tension headache and paediatric migraine.

85. Use according to claim 84, wherein said condition is migraine.

86. A process of preparing a pharmaceutically acceptable oral formulation according to any of claims 1 to 42, which process comprises providing core material which comprises a therapeutically effective amount of a 5-HT-receptor agonist, or a pharmaceutically acceptable salt, solvate or derivative thereof, and providing the core material with a substantially water resistant coating comprising one or more substantially water resistant materials.

87. A process according to claim 86, which employs wet granulation or direct compression techniques.